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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/574,819	05/19/2000	Frank P. Luyten	NIH0099.001C1	1648
45311	7590	02/15/2006	EXAMINER	
KNOBBE, MARTENS, OLSON & BEAR, LLP 2040 MAIN STREET FOURTEENTH FLOOR IRVINE, CA 92614			ROMEO, DAVID S	
			ART UNIT	PAPER NUMBER
			1647	

DATE MAILED: 02/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/574,819	LUYTEN ET AL.	
	Examiner	Art Unit	
	David S. Romeo	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 December 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 27-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 27-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/07/2005 has been entered.

Claims 27-32 are pending and being examined.

Maintained Formal Matters, Objections, and/or Rejections:

Claim Rejections - 35 USC § 102

Claim 27 is rejected under 35 U.S.C. 102(a) as being anticipated by Storm (Nature. 1994 Apr 14;368(6472):639-43).

Claim Rejections - 35 USC § 103

Claims 27-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Storm (Nature. 1994 Apr 14;368(6472):639-43) and Neidhardt (WO 93/16099).

Applicants argue that the declarations filed on 10/02/2003, 07/12/2004 and 12/07/2005 under 37 CFR 1.131 are able to antedate the Storm reference indirectly by showing prior completion of the bovine and Xenopus species, which put them in possession of the claimed genus defined by SEQ ID NO: 24 prior to April 14, 1994, the date of the Storm reference. The declarations filed on 10/02/2003, 07/12/2004 and 12/07/2005 under 37 CFR 1.131 have been considered but are ineffective to overcome the Storm reference.

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The declaration filed 10/02/2003 shows the completion of a partial bovine DNA sequence encoding a partial amino acid sequence comprising the amino acid sequence of SEQ ID NO: 24.

The declaration filed 07/12/2004 shows completion of the bovine species of the claimed invention.

5 The declaration filed 12/07/2005 shows the completion of a partial *Xenopus* DNA sequence encoding a partial amino acid sequence comprising the amino acid sequence of SEQ ID NO: 24.

 The claims are directed to or encompass a DNA molecule encoding a protein of the TGF- β family having chondrogenic activity *in vivo* and comprising the amino acid sequence of SEQ
10 ID NO: 24. The limitations “a protein of the TGF- β family” and “has chondrogenic activity” imply structure in addition to the amino acid sequence of SEQ ID NO: 24, as indicated in the Examiner Interview Summary of 12/08/2004 and in Applicants’ response filed 03/08/2005. In general, BMPs are dimeric molecules. The dimeric conformation is critical for biological action. BMP monomers are processed to yield the C-terminal mature monomer of 110+ amino acids.
15 See Reddi (Cytokine Growth Factor Rev. 1997 Mar;8(1):11-20) page 13, left column, last full paragraph. Thus, one would expect that an isolated DNA molecule which codes for a protein of the TGF- β family, wherein said protein has chondrogenic activity *in vivo*, as claimed, would code for a protein that is secreted as a dimer and then cleaved to result in a biologically active carboxy terminal domain of 110+ amino acids, characterized by 7 highly conserved cysteine
20 residues. However, the amino acid sequences in the declarations filed 10/02/2003 and 12/07/2005 show only a partial amino acid sequence, approximately 31 amino acids in length, of a TGF- β family member. One skilled in the art would not expect that these partial peptides

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would have chondrogenic activity *in vivo* because one would expect that an isolated DNA molecule which codes for a protein of the TGF- β family, wherein said protein has chondrogenic activity *in vivo*, would code for a protein that is secreted as a dimer and then cleaved to result in a biologically active carboxy terminal domain of 110+ amino acids, characterized by 7 highly conserved cysteine residues. No evidence has been brought forth that these partial peptides would provide a protein that has chondrogenic activity *in vivo*. Therefore, Applicants have not shown prior completion of one or more species which put them in possession of the claimed genus, i.e., a DNA molecule encoding a protein of the TGF- β family having chondrogenic activity *in vivo* and comprising the amino acid sequence of SEQ ID NO: 24, prior to Storm's date. However, it would appear that Applicants have shown completion of one or more species of DNA molecules encoding the amino acid sequence of SEQ ID NO: 24 prior to the date of the Storm reference. Consequently, it would appear that limiting the claims to an isolated DNA molecule encoding the amino acid sequence of SEQ ID NO: 24 would overcome the Storm reference. However, this would raise new prior art issues because Celeste (U. S. Patent No. 5,658,882, of record) discloses a DNA sequence (SEQ ID NO:12) and derived amino acid sequence (SEQ ID NO:13), which comprises the amino acid sequence of the present application's SEQ ID NO: 24. Celeste's disclosure has an effective filing date of 03/25/1994.

New Formal Matters, Objections, and/or Rejections:

Double Patenting

Claim 27 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 10 and 11 of copending Application No. 10379830. Although the conflicting claims are not identical, they are not patentably distinct

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from each other because the present claims are generic to and fully encompass the claims of the co-pending application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

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Conclusion

No claims are allowable.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Lee (U. S. Patent No. 5,770,444, of record) discloses and claims a DNA molecule encoding the amino acid sequence of SEQ ID NO: 6. See claim 2. Lee's SEQ ID NO: 6 comprises the present application's SEQ ID NO: 24.

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ANY INQUIRY CONCERNING THIS COMMUNICATION OR EARLIER COMMUNICATIONS FROM THE EXAMINER SHOULD BE DIRECTED TO DAVID S. ROMEO WHOSE TELEPHONE NUMBER IS (571) 272-0890. THE EXAMINER CAN NORMALLY BE REACHED ON MONDAY THROUGH FRIDAY FROM 7:30 A.M. TO 4:00 P.M. IF ATTEMPTS TO REACH THE EXAMINER BY TELEPHONE ARE UNSUCCESSFUL, THE EXAMINER'S SUPERVISOR, BRENDA BRUMBACK, CAN BE REACHED ON (571) 272-0961.

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IF SUBMITTING OFFICIAL CORRESPONDENCE BY FAX, APPLICANTS ARE ENCOURAGED TO SUBMIT OFFICIAL CORRESPONDENCE TO THE CENTRAL FAX NUMBER FOR OFFICIAL CORRESPONDENCE, WHICH IS (571) 273-8300.

CUSTOMERS ARE ALSO ADVISED TO USE CERTIFICATE OF FACSIMILE PROCEDURES WHEN SUBMITTING A REPLY TO A NON-FINAL OR FINAL OFFICE ACTION BY FACSIMILE (SEE 37 CFR 1.6 AND 1.8).

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ANY INQUIRY OF A GENERAL NATURE OR RELATING TO THE STATUS OF THIS APPLICATION OR PROCEEDING SHOULD BE DIRECTED TO THE GROUP RECEPTIONIST WHOSE TELEPHONE NUMBER IS (703) 308-0196.

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DAVID ROMEO
PRIMARY EXAMINER
ART UNIT 1647

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DSR
FEBRUARY 14, 2006